DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

PHILADELPHIA DISTRIC

900 U.S. Customhouse
2nd and Chestnut Streets
Philadelphia, PA 19106
Telephone: 215-597-4390

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

99-PHI-08

December 21, 1998

Robert Dunlap, Owner
Captain Bob's Seafood
609-6 West End Boulevard
Quakertown, PA 18951

Dear Mr. Dunlap:

During the period September 16-17, 1998, Colleen Damon, an Investigator for the U. S. Food & Drug Administration (FDA), conducted an inspection of your seafood processing firm. At the conclusion of the inspection you were issued a form FDA-483 which delineated a number of serious deficiencies in HACCP and sanitation procedures in your seafood processing facility. These deficiencies cause foods processed in your facility to be adulterated within the meaning of Section 402 (a)(4) of the Food, Drug and Cosmetic Act (the Act), in that products are adulterated by being prepared, packed or held under conditions whereby they may have become injurious to health.

1) Your HACCP plan addressed the hazard of histamine, but is inadequate for its control in that you are not monitoring and recording items as stated in your HACCP plan.
   A) The temperature of raw tuna is not taken and recorded upon receipt.

   B) The storage refrigerator temperature is not always taken and recorded twice daily as required by your HACCP plan. Your HACCP plan should state the approximate times that the temperature of the cooler will be taken, e.g., at the beginning of a shift.

2) Our investigator documented instances where sanitation conditions and practices are not monitored and documented as required by 21 CFR 123.11(b) & (c). For example:

   Condition of cleanliness of food contact surfaces. Although you indicated that records of cleaning are now being kept, the strength of the chlorine sanitizer and

the hand sanitizer are not monitored or recorded.

Cross contamination. Two hose bibs in the processing room do not have back flow preventers.

Protection from adulterants. Chipped paint and wood are exposed on the surface of the wall around the entryway to refrigerator #1.

Storage and use of toxic compounds was neither monitored nor recorded.

Adverse health conditions of employees were not monitored or recorded.

Pest control was not monitored or recorded.

2) The corrective actions described for the receiving critical control point and chilled storage critical control point are inappropriate and are inconsistent with your critical limit for rejection of 41 F. More importantly, re-icing does not address a histamine hazard that may have already developed in the product.

The above is not intended to be an all-inclusive list of deficiencies at your firm. As top management it is your responsibility to assure that all of your company's operations are in compliance with the FD&C Act and its associated regulations. We acknowledge your promise to the Investigator that you will correct all deficiencies observed. However, you should take prompt action to correct these deficiencies. Failure to correct them promptly may result in enforcement action without further notice, such as seizure and/or injunction. You should notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the attention of William W. Knipe, Compliance Officer, at the address noted above.

Sincerely,

W. Charles Becoat

W. Charles Becoat
Acting District Director